

## REMARKS

The present amendment and arguments are submitted in response to an office action issued on February 24, 2009. The application contains claims 43-50 and 73-93. Claims 43 and 85 are amended herewith. Claim 88 is amended to correct a typographical error in the claim. Claims 92 and 93 are new.

The amendment to claim 43 is supported at least by page 1, page 11, lines 14-15 and lines 30-32 and page 12, lines 1-3 of the application as filed. Support for new claim 92 is found at least on page 6, line 15 of the application as filed. Support for new claim 93 is found at least on page 7, lines 30-32 of the application as filed.

### **Drawings**

The drawings stand objected to under 37 CFR 1.83(a) since the connection of the external and internal sheath to the proximal connector (claim 79) must be shown or the feature cancelled from the claims. Applicants respectfully disagree with the objection. A proximal connector in the form of a proximal tube 110 is illustrated in Fig. 1A.

### **Claim Rejections 35 USC 112**

Claim 83 stands rejected under 35 USC 112 as failing to comply with the written description requirement. Claim 83 recites "wherein at least the distal ends of the internal and external sheaths are foldable". The Examiner stated that the specification only mentions the external sheath being foldable.

Applicants respectfully disagree. Claim 83 is supported by the specification at least on page 11, lines 14-15: "*In some embodiments of the invention, both the internal and external sheaths have substantially the same thickness and are formed from the same material.*" Thus, the specification states that the internal and external sheath may, according to some embodiments, have the same thickness and be made of the same material. As stated by the Examiner, the specification also clearly states that the external sheath may be foldable.

Accordingly, the specification teaches some embodiments according to which both internal and external sheath are foldable (at least at their distal end).

### **Claim Rejections 35 USC 102**

Claim 43 is the only independent claim in the application. The Examiner provided 5 different anticipation rejections to claim 43. Before relating to each rejection specifically, applicants present the following argument for patentability of claim 43 over all of the cited art.

Claim 43 is amended and now reads:

"A sheath assembly for a probe, comprising:  
an internal sheath configured to isolate a probe from body fluids; and  
an external sheath surrounding the internal sheath, the external sheath configured to define a channel for passing of fluids, tools or working tubes and the internal and external sheaths being connected to each other,  
wherein the internal sheath is bendable, configured to bend longitudinally around corners while the sheathed probe is inserted into a patient, and  
wherein the external sheath is folded during insertion into the body."

Applicants submit that none of the cited art shows or even suggests the combination of a bendable internal sheath with an external sheath that is folded during insertion into the body as claimed. The cited art either teaches either a rigid internal sheath which does not bend longitudinally around corners, or an elastic internal sheath which is not folded during insertion into the body but is collapsed and snugly fits around the endoscope so as not to increase the diameter of the internal sheath during insertion into the body.

Applicants will now refer to each of the rejections specifically.

Claims 43-45, 47, 49, 73-77, 79, 82-84 and 91 stand rejected under 35 USC 102(b) as being anticipated by Nakao et al. (US 5,217,001).

The Examiner rejected claim 43 under two different embodiments of Nakao. The embodiment shown in Figs. 7-10 and another embodiment shown in Figs. 12A-C.

Applicants submit that both embodiments of Nakao fail to teach an internal sheath and an external sheath as recited in amended claim 43.

The external sheath of Nakao in the embodiments of Figs. 7-10 are a plurality of flexible webs which are collapsed upon the outer surface of the internal sheath thereby minimizing at the outset of an endoscopic operation the effective outer diameter of the internal sheath, see col. 8, lines 39-48. The flexible webs of Nakao are adapted to expand by forcibly inserting endoscopic surgical instruments, see col. 8, lines 49-55. Thus, Nakao fails to teach an external channel which is folded during insertion into the body as required by claim 43. It is submitted that the flexible webs of Nakao **cannot** be folded during insertion into the body, since they are collapsed during insertion and snugly fit around the internal sheath, leaving no excess of sheath material to be folded.

Also the embodiments shown in Figs. 12A-C fail to teach an external sheath as claimed. The external sheath is rolled up to a ring member and must be unrolled before insertion into the body in order to define a channel. Upon unrolment, the sheath member is collapsed around the internal sheath and is expanded by endoscopic surgical instrument which are forcibly inserted when the endoscope is in the body, see col. 9, lines 25-41. Accordingly, the second embodiment of Nakao also fails to teach an external sheath as claimed in claim 43.

Thus, claim 43 and its dependent claims are patentable over Nakao.

Claims 43, 43, 80, 85 and 90 stand rejected under 35 USC 102(b) as being unpatentable over Bacich et al. (US 5,749,889).

Applicants respectfully submit that Bacich fails to teach an external sheath as recited in claim 43. The first (internal) channel in Bacich is a rigid channel which is not configured to bend longitudinally around corners while the sheathed probe is inserted into a patient as required by claim 43.

It is submitted that the use of rigid internal channels such as Bacich provide better control of the sheathed probe. Thus, although Bacich mentions the need for flexible channels, he addresses this need by a flexible secondary channel which is attached to an inner rigid channel, see col. 3, lines 27-34 and col. 8, lines 1-5.

Accordingly, applicants submit that claim 43 and its dependent claims are patentable over Bacich.

Claims 43 and 87 stand rejected under 35 USC 102(b) as being unpatentable over Silverstein et al. (US 5,025,778).

Applicants respectfully submit that Silverstein fails to teach at least one feature of amended claim 43, namely "the external sheath is folded during insertion into the body".

The external sheath taught by Silverstein is a radially flexible wall which is collapsed prior to insertion into the body, see abstract. The flexible wall is expanded to form a channel when it is positioned in the body and a tool or fluid is inserted into the channel under pressure. Thus, the flexible wall of Silverstein is not and **cannot** be folded during insertion into the body, as in its collapsed state the cross-section of the flexible wall is substantially the same as that of the endoscope, and therefore has no extra material to be folded, see co. 2, lines 45-50.

Furthermore, applicants submit that the internal channel of Silverstein is not "bendable, configured to bend longitudinally around corners while the sheathed probe is inserted into a patient" as recited in claim 43. The substantial force required in order to expand the flexible outer channel of Silverstein would distort the layout of the endoscope if it were not rigid.

In view of the above it is submitted that Silverstein fails to teach the features of claim 43 and therefore claim 43 and its dependent claims are patentable over Bacich.

Claims 43, 48, 50, 78, 81 and 86 stand rejected under 35 USC 102(b) as being anticipated by Krasner et al. (US 4,676,228).

Claims 43 and 48 stand rejected under 35 USC 102(e) as being anticipated by Oneda et al. (US 6,461,294 herein referred Oneda1).

Claim 43 was amended to make explicit what was already implicit, namely that the external sheath is configured to define a channel for passing of fluids, tools or working tubes. It is submitted that the external sheaths of both Krasner and Oneda1 are not configured to define a channel for passing of fluids, tools or working tubes but rather for navigating the endoscope through the lumen (Krasner) or for maintaining the endoscope in a selected location within a body passage (Oneda1).

Accordingly, neither Krasner nor Oneda1 render claim 43 or its dependent claims unpatentable.

In addition, new dependent claims 92 and 93 provide further patentability over Krasner and Oneda. Claim 92 recites "*wherein the external sheath extends over at least 50% of the internal sheath.*" Claim 93 recites "*wherein the internal sheath and external sheath coextend at their distal ends, such that their distal ends extend to a same point.*"

The external sheaths of both Krasner and Oneda1 are substantially shorter than 50% of the external sheath and therefore do not meet the requirements of new claims 92 and 93.

### **Claim Rejections 35 USC 103**

Claim 88 stands rejected under 35 USC 103(a) as being unpatentable over Silverstein in view of Nakao. Claim 88 recites that "the internal and external sheath are formed from the same material".

According to the Examiner, Silverstein teaches that the external member may be made of rubber but does not disclose the material of the internal sheath. Nakao discloses an analogous device which uses rubber as the material for the internal sheath. The Examiner

contends that it would have been obvious to modify Silverstein's internal sheath so that it is made of rubber.

Applicants respectfully disagree and submit that the Examiner has not provided a *prima facie* case of obviousness since the combination suggested by the Examiner would not function. As recited by applicants above, the inner sheath of Silverstein must be rigid as otherwise the forces used for expanding the outer channel would distort the layout of the endoscope. Accordingly, applicants submit that claim 88 is patentable over the cited art.

Claim 89 stands rejected under 35 USC 103(a) as being unpatentable over Silverstein in view of Oneda et al. (US 6,174,280 herein referred to as Oneda2).

Claim 89 depends on claim 43 and is patentable at least by virtue of its patentable parent claim.

### **Conclusion**

In view of the above amendments and arguments, applicants submit that independent claim 43 and dependent claims 44-50 and 73-91 are patentable over the cited art. Notice thereof is respectfully awaited.

Respectfully submitted,

**/Jason H. Rosenblum/**

Jason H. Rosenblum  
Registration No. 56,437  
Telephone: 718.246.8482

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